No. 90-1305

Supreme Court, U.S.
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IN THE

# Supreme Court of the United States

OCTOBER TERM, 1990

ERNEST BERGER, Personal Representative
of the Estate of SHEILA BERGER,

*Petitioner*,

—v.—

PERSONAL PRODUCTS, INC., et al.,

*Respondents.*

ON PETITION FOR A WRIT OF CERTIORARI
TO THE WASHINGTON STATE SUPREME COURT

## BRIEF IN OPPOSITION

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## QUESTION PRESENTED

Respondents reformulate the question presented as follows:

> Does federal law preempt a state tort action based on the claims of inadequate warnings and instructions about the risk of contracting toxic shock syndrome associated with tampon use when the product complies with federal labelling requirements?

## PARTIES

Petitioner is Ernest Berger as Personal Representative of the Estate of Sheila Berger.

Respondents are Johnson & Johnson (misnamed in Washington Supreme Court opinion as "Johnson and Johnson, Inc."), Personal Products Company (misnamed in Washington Supreme Court opinion as "Personal Products, Inc."), and Johnson & Johnson Medical, Inc., f/d/b/a Johnson & Johnson Products, Inc. Johnson & Johnson is a corporation organized and existing under the laws of New Jersey with its principal place of business in New Brunswick, New Jersey. It is a publicly held corporation. Johnson & Johnson has no parent corporation and has no subsidiaries or affiliates other than wholly-owned subsidiaries. Personal Products Company, a division of McNeil-PPC, Inc., and Johnson & Johnson Medical, Inc. are wholly-owned subsidiaries of Johnson & Johnson.

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ON PETITION FOR A WRIT OF CERTIORARI
TO THE WASHINGTON STATE SUPREME COURT

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## BRIEF IN OPPOSITION

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TO: The Honorable Chief Justice and Associate Justices of the Supreme Court of the United States:

Respondents Johnson & Johnson, Personal Products Company, and Johnson & Johnson Medical, Inc. (collectively, "Personal Products Co.") respectfully submit that certiorari should not be granted in this case. In a unanimous *en banc* decision, the Washington State Supreme Court held that a state tort action based on the claims of inadequate warnings and instructions concerning the risk of contracting toxic shock syndrome ("TSS") associated with tampon use are preempted by federal law when the product complies with federal labelling requirements. That decision is consistent with

precedent from this Court mandating preemption of state law where Congress or a federal regulatory agency has expressed an intent to preempt. The decision is also in accord with the decisions of every other appellate court—both state and federal—that has considered this precise question.[1]

Petitioner's argument against preemption—and for this Court's review—depends upon an oversimplified and misconceived version of the law. In the Medical Devices Amendments ("MDA") of 1976 to the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the regulations promulgated thereunder, 21 CFR Part 800 *et seq.*, Congress and the Food and Drug Administration ("FDA") have expressed an intent to preempt state law where a manufacturer has complied with specific regulations concerning a medical device. There is no question that the FDA's regulations concerning tampon warnings and instructions are specific requirements concerning tampons and that tampons are classified as medical devices. In addition, there is no question that respondents complied with the federal regulations governing tampon warnings and instructions. Thus the Washington Supreme Court decision is plainly correct in finding in favor of preemption.

Because the decision of the Washington Supreme Court correctly applies this Court's precedents, and because its holding is consistent with every other appellate decision addressing the issue, there is no reason for this Court to grant certiorari.

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1 A list of the decisions that are consistent with the Washington Supreme Court's decision is contained in Appendix A.

## STATEMENT OF THE CASE

The petition requests review of the Washington Supreme Court's unanimous *en banc* affirmance of the trial court's grant of partial summary judgment. *Berger v. Personal Products, Inc.*, 115 Wash. 2d 267, 797 P.2d 1148 (1990). In granting partial summary judgment, the trial court dismissed that portion of petitioner's product liability claim that was based on the alleged failure of Personal Products Co. to adequately warn its tampon users of the risk of TSS. Following a host of prior decisions directly on point, the Yakima County Superior Court ruled that federal law—21 U.S.C. § 360k(a) and the relevant regulations promulgated by the FDA—preempts state tort claims for inadequate TSS warnings and instructions where a manufacturer has complied with federal regulatory standards. *Berger v. Johnson & Johnson Products, Inc.*, No. 86-2-01249-3 (Sup. Ct. Yakima Co. Wash. March 14, 1989).

This decision was then reviewed and unanimously affirmed by the Washington Supreme Court. The Court's decision is consistent with the decisions of thirty-five other courts that have considered this precise issue.

In seeking a writ of certiorari, petitioner attempts to erect and defeat a straw man. Petitioner misreads the *Berger* decision as holding that the MDA preempts *all* state law claims. After positing this fictional "holding," petitioner then attacks it by relying on cases that do *not* involve the FDA's regulations concerning tampons or TSS and by relying on cases that do *not* involve interpretation of the MDA. These cases are not on point.

The Washington Supreme Court's decision does not broadly displace all state tort law. It does not hold that tort claims based on an alleged failure to comply with federal regulations concerning tampon warnings are preempted, and it does not suggest that tort claims based on design defect are displaced. In fact, petitioner had asserted a design defect

claim before the trial court and then voluntarily dismissed that claim.

What the *Berger* decision, and every other reasoned decision on this issue, asserts is consistent with what the FDA has determined in its regulations, *i.e.*, that state requirements are preempted "only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act . . . ." *Berger v. Personal Products, Inc.*, *supra*, 115 Wash. 2d at 273, 797 P.2d at 1151, *quoting Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 244-45 (5th Cir. 1989). Because the decisions on the preemption of state law claims concerning tampon warnings are consistent, clear, and correct, there is no reason for this Court to grant certiorari to review this case.

## REASONS FOR DENYING THE WRIT

### I. The *Berger* Decision Does Not Raise a Significant Issue Concerning the Supremacy Clause and a State's Right to Provide Tort Claims

#### A. Under the Constitution's Supremacy Clause, Federal Law May Explicitly or Implicitly Preempt State Law, Including State Tort Claims

It is a "familiar and well-established principle that the Supremacy Clause, U.S. Const., art. VI, cl. 2, invalidates state laws that 'interfere with, or are contrary to,' federal law." *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 712 (1985), *quoting Gibbons v. Ogden*, 9 Wheat. 1, 211 (1824). This Court has repeatedly recognized a variety of ways in which federal law may displace state law. *See generally California Coastal Comm'n v. Granite Rock Co.*, 480 U.S. 572, 581 (1987); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984). "Preemption may be either express or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's lan-

guage or implicitly contained in its structure and purpose.' " *Fidelity Fed. Sav. and Loan Ass'n v. De La Cuesta*, 458 U.S. 141, 152-53 (1982), *quoting Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

Although the case involves express preemption, Congress' intent to displace state law may be implied because the federal regulatory scheme is so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it or because the federal regulation touches a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject or because the object sought to be obtained by federal law and the character of obligations imposed by it may reveal the same purpose. *Jones v. Rath Packing Co.*, *supra*, 430 U.S. at 525; *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Moreover, state law can be preempted by federal regulations as well as by federal statutes. *See Louisiana Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 369 (1986); *Hillsborough County v. Automated Medical Laboratories, Inc.*, *supra*, 471 U.S. at 713; *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 699 (1984); *Fidelity Fed. Sav. & Loan Ass'n v. De La Cuesta*, *supra*, 458 U.S. 141.

Even where federal regulations have not completely displaced state regulation in a specific area, state law is supplanted to the extent that it actually conflicts with federal law—that is, where "compliance with both federal and state regulations is a physical impossibility," *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963), or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). In this case, because Congress and the FDA expressed an intent to preempt state law, there is no need to consider these issues of implied preemption.

Petitioner is plainly wrong in suggesting that common law claims brought in state court can never be preempted. As this Court has stated,

> [R]egulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy. Even the States' salutary effort to redress private wrongs or grant compensation for past harm cannot be exerted to regulate activities that are potentially subject to the exclusive federal regulatory scheme.

*San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959). *See International Paper Co. v. Ouellette*, 479 U.S. 481 (1987) (holding that, in the circumstances presented, a claim for damages and injunctive relief under Vermont's common law of nuisance was preempted by the Clean Water Act). *Chicago & N.W. Trans. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 326-27 (1981). *See also Silkwood v. Kerr-McGee Corp.*, *supra*, 464 U.S. at 256.

### B. The Federal Regulatory Scheme at Issue Preempts Differing or Additional State Law Requirements Concerning the Adequacy of Tampon Warnings

#### 1. Congress and the FDA Intended to Preempt State Law Where the FDA Promulgates Specific Device Requirements

In this case, the preemption analysis begins with the 1976 Medical Device Amendments to the FDCA, 21 U.S.C. § 301 *et seq.* According to the Senate Committee Report that reviewed it, the MDA's purpose was to encourage the research and development of increasingly sophisticated and critically important medical devices, as well as to ensure that "the FDA has the proper authority to regulate that process so that Americans are not put at risk from the use of unsafe and ineffective medical devices." S. Rep. No. 33, 94th Cong., 1st Sess. (1975), *reprinted in* 1976 U.S. Code Cong. & Admin. News 1070, 1071. Congress also sought to ensure that, once the FDA had addressed an issue of safety or efficacy, a state could not create an undue burden by imposing other requirements:

> The Committee recognizes that if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.

H.R. Rep. No. 853, 94th Cong., 2d Sess., at 45 (1976). As one court stated, Congress intended "to prohibit, by the doctrine of express preemption, the proliferation of multiple, diverse, state by state requirements." *Stewart v. International Playtex, Inc.*, 672 F. Supp. 907, 909 (D.S.C. 1987).

Under the MDA, the FDA is authorized to classify medical devices in three categories, depending upon the sufficiency of information concerning their safety and efficacy. 21 U.S.C. § 360. The MDA delegated to the FDA the power to establish "performance standards" with regard to all devices categorized in Class II. 21 U.S.C. § 360d(a)(1).

The preemptive effect of the FDA performance standards is established in § 360k(a) of the MDA:

> (a) General Rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(*See* Appendix B). A state, or a political subdivision, may avoid preemption by applying for an exemption pursuant to § 360k(b), but that provision is not at issue here because Washington State has not applied for an exemption as to state law remedies regarding tampon labelling.

Pursuant to the MDA, the FDA promulgated specific regulations addressing preemption. 21 C.F.R. Part 808. The FDA regulations provide that

> [s]tate or local requirements are preempted only when the Food and Drug Administration has established *specific counterpart regulations* or there are *other specific requirements applicable* to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. . . .

21 C.F.R. § 808.1(d) (emphasis added) (*See* Appendix C).

To the extent that the FDA's regulations preempt state law, there is no question that the preemption includes court decisions. First, as noted above, it is well established that the preemption doctrine applies to supersede common law claims brought in state court. *San Diego Bldg. Trades Council v. Garmon*, *supra*, 359 U.S. at 247; *International Paper Co. v. Ouellette*, *supra*, 479 U.S. 481; *Chicago & N.W. Trans. Co. v. Kalo Brick & Tile Co.*, *supra*, 450 U.S. at 326-27; *Silkwood v. Kerr-McGee Corp.*, *supra*, 464 U.S. at 256. Second, the FDA explicitly included court decisions in the ambit of state requirements that would be preempted by its regulations. 21 C.F.R. § 808.1(b) (Appendix C). In relevant part, that regulation provides that after the effective date of the MDA,

> no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(Emphasis added.)

There can be no clearer statement by Congress or the FDA of an intent to preempt state law—including state tort claims—with regard to any medical device for which the FDA establishes specific requirements.

### 2. The FDA Promulgated Regulations Containing Specific Requirements Concerning Tampon Warnings, Thereby Preempting State Law

In February 1980, the FDA classified tampons as Class II medical devices. 21 C.F.R. §§ 884.5460 and 884.5470 (*See* Appendix D). Subsequently, on June 22, 1982, the FDA promulgated a regulation setting forth specific and mandatory labelling requirements regarding the risk of TSS associated with tampon use. 21 C.F.R. § 801.430 (*See* Appendix E). That regulation *requires* that specific language be included both in and on every package of tampons, and it mandates that such warning *shall appear* prominently and legibly on the package label.[2]

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2 At the time relevant to this action, that regulation stated in pertinent part as follows:

(c) If the information specified in paragraph (d) of this section is to be included as a package insert, the following alert statement *shall* appear prominently and legibly on the package label:

Attention: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.

(d) The consumer information required by this section *shall* appear prominently and legibly, in a package insert on the package, in terms understandable by the layperson and *shall* include statements concerning:

(1)(i) Warning signs to TSS, e.g., sudden fever (usually 102° or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;

(ii) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;

(2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to

There is no question that the FDA's regulation of tampon warnings is a "requirement" within the meaning of 21 C.F.R. § 808.1(b) and (d), quoted *supra*, which provide for preemption of state or local requirements relating to tampon labelling. Accordingly, all state law requirements regarding the adequacy of tampon labelling with respect to TSS warnings, including court decisions, are preempted where the manufacturer has complied with the FDA's regulations. 21 U.S.C. § 360k(a); 21 C.F.R. § 808.1(b).

### C. The Federal Regulatory Scheme Expressly Preempts Competing Requirements Established by State Product Liability Law Concerning Tampon Warnings

Petitioner argues that the MDA does not expressly preempt all state product liability law and hence state tort actions based on inadequate tampon warnings claims are not preempted. Respondents agree that the MDA does not automatically displace all state tort law. What the MDA does is

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women under 30 years of age and teenage girls, the estimated incidence of TSS of 6 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;

(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow;

(4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and possibly reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and

(5) The need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.

. . .

(f) Any menstrual tampon that is not labeled as *required* by this section and that is initially introduced or initially delivered for introduction into commerce after December 20, 1982, is misbranded pursuant to sections 502(a) and 201(n) of the act.

(Emphasis added.) The FDA has subsequently amended this regulation. A copy of the 1990 amended regulation is produced at Appendix F.

provide the framework requiring preemption when the FDA promulgates specific requirements for medical devices. Petitioner's argument simply ignores the FDA's specific regulations that *do* expressly preempt state law claims for tampon warnings that comply with FDA regulations. It is those regulations, promulgated with proper authority, that mandate preemption in this case.

Petitioner also ignores the substantial body of law that uniformly interprets those precise regulations as preempting state product liability claims based on the adequacy of tampon warnings. As the Washington Supreme Court and many other courts have determined, those regulations reflect the "expression of intent to preempt state law." *Berger v. Personal Products, Inc.*, *supra*, 115 Wash. 2d at 271, 797 P.2d at 1150. (*See also* decisions listed in Appendix A.)

Petitioner cannot find support for its position in the language or history of either the MDA or the regulations promulgated thereunder. Unable to find support in the one statute that governs this case, petitioner turns to other statutes that are not controlling here. Thus petitioner argues that the legislative history of the 1938 FDCA does not show an intent to preempt state law. That argument is misplaced. The relevant statute is the MDA, not the FDCA of 1938. The FDCA history was superseded in 1976 when Congress enacted the MDA, which explicitly preempts state law where such law is inconsistent with FDA regulations. 21 U.S.C. § 360k(a) (Appendix B). Pursuant to authority conferred by the MDA, the FDA determined to preempt all competing state regulation, including court decision, by promulgating specific requirements for medical devices. 21 C.F.R. § 808.1(b) (Appendix C). The FDA has, in fact, promulgated a detailed requirement on tampon warnings and instructions. 21 C.F.R. § 801.430 (Appendix E). The history of the 1938 FDCA that petitioner cites has no bearing on the preemptive effect of regulations promulgated under authority granted by a later Congress, and this Court should not grant review based on irrelevant legislative history. *See Hillsborough County v. Automated Medical Laboratories, Inc.*, *supra*, 471 U.S. at

714 (suggesting that subsequent history revealing a change in Congress' or the FDA's position supersedes previous history).

Turning even further afield, petitioner also attempts to rely on the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") and a case decided under FIFRA. *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984). That reliance is equally misplaced. FIFRA established minimum requirements for labeling claims and it did not preempt a state's right to set higher standards. Moreover, FIFRA has its own regulatory and legislative history, and it is absurd to suggest that the FDA—and this Court—should be bound by the interpretations of this entirely different statute. Lastly, a recent Eleventh Circuit decision expressly rejected *Ferebee* and held that FIFRA had implicitly preempted state tort claims based on labelling. *Papas v. The Upjohn Company*, No. 89-3752, 1991 U.S. App. LEXIS 3277 (11th Cir. Feb. 28, 1991). Thus, *Ferebee* is not only not on point, but it is also of questionable precedential value.

In contrast to regulations promulgated under FIFRA, which set only minimum requirements, the FDA's regulations concerning warning requirements on tampon packaging for TSS are detailed, exacting and exclusive. *See, e.g., Stewart v. International Playtex, Inc., supra*, 672 F. Supp. at 910 (distinguishing *Ferebee* because of the differences between the regulatory scheme promulgated under the MDA and regulations dealing with pesticide labelling). Those requirements dictate the exact language and content of the TSS warnings which must appear on and in all boxes of tampons. The *Berger* decision was correct in finding that competing state standards cannot stand without imposing an undue burden on commerce. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess., at 45 (1976) (Congress sought to prevent "a substantial number of differing requirements applicable to a medical device . . . imposed by jurisdictions other than the Federal government").

## II. There is No Conflict Between *Berger* and any Other Decision Warranting this Court's Review

### A. There is No Conflict Among the Appellate Courts that Have Considered the Preemptive Effect of the FDA's Tampon Regulations

The Washington Supreme Court's decision in *Berger* is consistent with the only federal Court of Appeals that has examined this precise issue. *Moore v. Kimberly-Clark Corp.*, *supra*, 867 F.2d 243. The *Berger* decision is also consistent with the only state court of last resort that has considered this issue. *Poloney v. Tambrands, Inc.*, 399 S.E.2d 208 (Ga. 1991). Both *Moore* and *Poloney* hold that where a manufacturer complies with federal regulations concerning warnings for TSS on tampon packaging, state law for inadequate warnings is preempted by federal law. Thus, there is no conflict between the *Berger* decision and any decision from a federal Court of Appeals or a state court of last resort warranting this Court's review.

In addition, thirty-five other federal district courts and lower state courts have also considered this issue; thirty-three have found that the federal regulations preempt state law concerning the adequacy of the TSS warnings on tampon packages. (*See* decisions listed in Appendix A.)

Of the thirty-eight decisions that have addressed the issue, only two lower court decisions, both unpublished, have held that the federal scheme does not preempt state law regarding tampon warnings. Neither decision is well-reasoned.[3] More-

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3 One of those cases, *Muzatko v. International Playtex, Inc.*, No. 85-C 1540 (E.D. Wis. May 14, 1987), relied on *O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1428 (10th Cir. 1987), *cert. denied*, 486 U.S. 1032 (1988), which did not even address this issue. *See infra* p. 15. Thus, it is utterly unpersuasive. *See Berger v. Personal Products, Inc.*, *supra*, 115 Wash. 2d at 274-75, 797 P.2d at 1151-52; *Ignace v. International Playtex, Inc.*, No. 86-C-480C, *slip op.* at 13, n.5 (W.D. Wis. Aug. 14, 1987); *Lavetter v. International Playtex*, 706 F. Supp. 722,

over, these two aberrational decisions cannot be considered a conflict in the face of thirty-six consistent decisions.[4] It is thus easy to understand why petitioner did not address either decision.

### B. Other Cites that Petitioner Relies Upon Fail to Create a Conflict with the *Berger* Decision

Petitioner ignores the consistent body of cases that have considered FDA regulations covering tampons and TSS, and instead attempts to invoke this Court's discretionary review

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723 (D. Ariz. 1988); *Stucker v. International Playtex, Inc.*, No. C87-0440-L(B), *slip op.* at 5-6 (W.D. Ky. Feb. 26, 1988). In addition, *Muzatko* has not been followed by any subsequent court, including two sitting in the same state. *See Ignace v. International Playtex, Inc.*, *supra*, No. 86-C-480C; *Mishlove v. Herman, M.D.*, No. 009-450 (Cir. Ct. Milwaukee Co. Wis. Nov. 29, 1989). *See also Bowden v. Tambrands, Inc.*, No. 85L 21095 (Cir. Ct. Cook Co. Ill. July 9, 1990) (declining to follow *Muzatko*).

The court in the other decision, *Kerns v. International Playtex, Inc.*, No. C-1-86-297, slip op. at 2 (S.D. Ohio Apr. 15, 1988), denied partial summary judgment on the issue of TSS warning stating that, because other issues remained open in the case, "[t]he granting of a partial summary judgment, in view of the differing judicial decisions, would lend little to a just final determination of this dispute among the parties and, as a practical matter, would not shorten the trial or lessen the parties' obligation to present evidence." This is not a reasoned opinion, and no court has followed it.

4 Even if the two district court decisions were inconsistent with the *Berger* decision, they would not create a conflict so as to warrant this Court's discretionary jurisdiction. *See* Sup. Ct. R. 10.1(b) (indicating that this Court will not generally grant jurisdiction unless a decision from a state court of last resort on a federal question "conflicts with the decision of another state court of last resort or of a United States court of appeals"). *See also Forsyth v. Hammond*, 166 U.S. 506, 513-15 (1897) (per Brewer, J.) (stating that this Court's certiorari jurisdiction "is a power which will be sparingly exercised, and only when the circumstances of the case satisfy us that the importance of the question involved, the necessity of avoiding conflict between two or more Courts of Appeal, or between Courts of Appeal and the courts of a State, or some matter affecting the interests of this nation in its internal or external relations, demands such exercise").

relying on two inapposite decisions involving hearing aid regulations. In *Smith v. Pingree*, 651 F.2d 1021 (5th Cir. 1981), and *New Jersey Guild of Hearing Aid Dispensers v. Long*, 75 N.J. 544, 384 A.2d 795 (1978), the courts held that state laws governing the dispensing and fitting of hearing aids were not preempted by FDA regulations. Neither of those decisions are applicable here because the FDA had not promulgated specific requirements in those areas. *Smith v. Pingree*, *supra*, 651 F.2d at 1021, 1025; *New Jersey Guild of Hearing Aid Dispensers v. Long*, *supra*, 384 A.2d at 811-12.

The Fifth Circuit in *Moore v. Kimberly-Clark Corp.*, *supra*, 867 F.2d at 246-47, found this distinction to be critical in a case involving the preemptive effect of the FDA's regulation concerning tampon warnings. It held that, unlike the hearing aid regulations at issue in *Smith*, state law claims based on inadequate tampon labelling and warnings concerning TSS were preempted because the FDA had promulgated specific requirements controlling tampon warnings.

Petitioner next attempts to create a conflict between *Berger* and a Tenth Circuit decision that affirmed a jury verdict in a TSS case. *O'Gilvie v. International Playtex, Inc.*, *supra*, 821 F.2d 1428. However, as the Washington Supreme Court and other courts have recognized, the issue of preemption was not raised in that case. *Berger v. Personal Products, Inc.*, *supra*, 115 Wash. 2d at 275, 797 P.2d at 1152; *Stewart v. International Playtex, Inc.*, *supra*, 672 F. Supp. at 910; *Lavetter v. International Playtex*, *supra*, 706 F. Supp. 722. The *O'Gilvie* decision is not on point and does not conflict with the holding in *Berger*.

Petitioner also asserts that there is a conflict between *Berger* and letters written by FDA staff members. Resort to such communications highlights the inherent lack of merit in the petition. According to FDA regulations, any opinion rendered by a staff member of the FDA "does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed." 21 C.F.R. § 10.85(k). Moreover, these letters

merely state that general tort remedies are not preempted by the MDA. Regardless of petitioner's attempts to stretch these letters, they *do not* conflict with the Washington Supreme Court's decision—indeed, these letters do not even address the preemptive effect of the specific requirements regulating tampon warnings.

Similarly, an FDA advisory opinion offered by petitioner, *see* Petitioner's Appendix at 17a-18a, fails to create a conflict. That opinion merely states that state law remedies available to those injured by Dalkon shield IUDs marketed *before* the MDA was passed are not preempted by the subsequent passage of the MDA. Rather than supporting the petitioner, this advisory opinion aids the respondents by emphasizing that state law requirements are preempted "when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of devices under the act. . . ." Pet. Appendix at 18a.[5]

Finally, contrary to petitioner's claims, the *Berger* decision is consistent with this Court's opinion in *Silkwood v. Kerr-McGee Corp.*, *supra*, 464 U.S. 238. In that decision, this Court found that Congress had not intended to preempt state law remedies that were available to those injured by nuclear incidents. In reaching this conclusion, this Court relied on the legislative history of the Price-Anderson Act, in which Congress specifically considered the survival of state law remedies for those who are injured by nuclear accidents. *Id.* at 252. The Court held that the state law remedies were not preempted because the possibility of conflict created by a state decision "was something that Congress was quite willing to accept." *Id.* at 256.

Unlike the legislative intent at issue in *Silkwood*, both Congress and the FDA have expressed a clear intent in the MDA and in the regulations promulgated thereunder to preempt

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5 In support of this clearly correct interpretation, respondents have attached to this brief as Appendix G a letter written by the FDA's Chief Counsel attesting that the question of preemption depends upon the circumstances of each particular case.

state law claims with regard to requirements established for medical devices. Thus, there is no conflict between *Silkwood* and *Berger*.

* * *

The Washington State Supreme Court and thirty-five other courts have agreed that where a manufacturer complies with detailed federal regulations, state tort claims based on the adequacy of tampon warnings are expressly preempted by federal law. This uniform view is consistent with this Court's preemption decisions. None of the appellate courts that have analyzed the issue have reached a contrary conclusion, nor could a contrary conclusion be reached upon consideration of the statutory and regulatory schemes. Accordingly, there is no reason for this Court to grant the petition.

## CONCLUSION

For all reasons set forth above, the petition for Writ of Certiorari should be denied.

Respectfully submitted,

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# APPENDICES

## Courts Finding Preemption of State Law Claims Regarding Tampon Warnings

### Federal Court of Appeals

1. *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989)

### District Courts

2. *Ignace v. International Playtex, Inc.*, No. 86-C-480C (W.D. Wis. Aug. 14, 1987)
3. *Edmondson v. International Playtex, Inc.*, 678 F. Supp. 1571 (N.D. Ga. 1987)
4. *Stewart v. International Playtex, Inc.*, 672 F. Supp. 907 (D.S.C. 1987)
5. *Perrotta v. International Playtex, Inc.*, No. 86-8099-CIV-KEHOE (S.D. Fla. Nov. 9, 1987)
6. *Moore v. Kimberly-Clark Corp.*, 676 F. Supp. 731 (W.D. La. 1987), *aff'd in part and rev'd in part*, 867 F.2d 243 (5th Cir. 1989)
7. *Lavetter v. International Playtex, Inc.*, 706 F. Supp. 722 (D. Ariz. 1988)
8. *Stucker v. International Playtex, Inc.*, No. C-87-0440-L(B) (W.D. Ky. Feb. 26, 1988), *rev'd on other grounds*, 865 F.2d 261 (6th Cir. 1988)
9. *Briggs v. International Playtex, Inc.*, No. 86C-540-E (N.D. Okla. Apr. 7, 1988)
10. *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475 (S.D. Ind. 1988)
11. *Needham v. International Playtex, Inc.*, No. 87-152 (E.D. Ky. Oct. 25, 1988), *aff'd on reconsideration*, 1989 U.S. Dist. LEXIS 800 (Jan. 26, 1989)
12. *Gilbert v. Kimberly-Clark Corp.*, No. 87-C-470-E (N.D. Okla. Nov. 4, 1988)

13. *Meyer v. International Playtex, Inc.*, 724 F. Supp. 288 (D.N.J. 1988)

14. *Jones v. Tambrands, Inc.*, No. C87-0102 (N.D. Iowa Dec. 2, 1988)

15. *Cornelison v. Tambrands, Inc.*, 710 F. Supp. 706 (D. Minn. 1989)

16. *Bejarano v. International Playtex, Inc.*, 750 F. Supp. 443 (D. Idaho 1989)

17. *Parrott v. International Playtex, Inc.*, No. SA CV 88-491 JSL (RWRx) (C.D. Cal. May 15, 1989)

18. *Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058 (D. Minn. 1989)

19. *Rockett v. International Playtex, Inc.*, No. 87-2870 (W.D. La. Oct. 2, 1989)

20. *Chapman v. Playtex FP, Inc.*, No. 89-0718-LC (W.D. La. Nov. 17, 1989)

21. *Krause v. Kimberly-Clark Corp.*, 749 F. Supp. 164 (W.D. Mich. 1990)

22. *Northrip v. International Playtex, Inc.*, 750 F. Supp. 402 (W.D. Mo. 1990)

STATE COURTS

23. *Berger v. Personal Products, Inc.*, 115 Wash. 2d 267, 797 P.2d 1148 (Wash. 1990)

24. *Poloney v. Tambrands, Inc.*, 399 S.E.2d 208 (Ga. 1991)

25. *Craig v. Kimberly-Clark Corp.*, No. 86-2-14780-2 (Sup. Ct. King Co. Wash. Sept. 15, 1988)

26. *Eason v. Tambrands, Inc.*, No. 87-11677-A (Dist. Ct. Dallas Co. Tex. Nov. 29, 1988)

27. *Laughlin v. Kimberly-Clark Corp.*, No. 17715 T.D.-1 (Cir. Ct. Memphis, Tenn. Dec. 7, 1988)

28. *Case v. International Playtex, Inc.*, No. C 607960 (Sup. Ct. Maricopa Co. Ariz. Jan. 23, 1989)

29. *Berry v. Tambrands, Inc.*, Nos. 193692, 193724 (Sup. Ct. Kern Co. Cal. Feb. 27, 1989)

30. *Berger v. Personal Products, Inc.*, No. 86-2-01249-3 (Sup. Ct. Yakima Co. Wash. Mar. 14, 1989) (Memorandum Opinion), *aff'd*, 115 Wash. 2d 267, 797 P.2d 1148 (1990)

31. *Remer v. Tampax, Inc.*, No. 578755 (Sup. Ct. San Diego Co. Cal. May 10, 1989)

32. *Aase v. Tambrands, Inc.*, No. 68108 (Dist. Ct. Kootenai Co. Idaho Aug. 24, 1989)

33. *Mishlove v. Herman, M.D.*, No. 009-450 (Cir. Ct. Milwaukee Co. Wis. Nov. 29, 1989)

34. *Poloney v. Tambrands, Inc.*, No. 88-1-1084-10 (Sup. Ct. Cobb Co. Ga. Apr. 16, 1990), *aff'd*, 399 S.E.2d 208 (Ga. 1991)

35. *Bowden v. Tambrands, Inc.*, No. 85 L 21095 (Cir. Ct. Cook Co. Ill. July 9, 1990)

36. *Byrne v. International Playtex, Inc.*, No. 86309 (Nineteenth Jud. Cir. Va. July 24, 1990) (Letter Ruling)

37. *Joliff-Smith v. Tambrands, Inc.*, No. 165928 (Sup. Ct. Sonoma Co. Cal. Nov. 7, 1990)

38. *Platts v. Tambrands, Inc.*, No. 901712 (Sup. Ct. San Francisco Co. Cal. Jan. 16, 1991)

# FOOD, DRUG, AND COSMETIC ACT, 21 U.S.C.

## § 360k. State and local requirements respecting devices

### (a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

### (b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

(June 25, 1938, c. 675, § 521, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 574.)

## FOOD AND DRUGS, 21 CFR Ch. 1

# PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

* * *

### Subpart A—General Provisions

**§ 808.1 Scope**

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an

exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or

related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b *et seq.*)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

[43 FR 18665, May 2, 1978, as amended at 45 FR 67336, Oct. 10, 1980]

* * *

**§ 884.5460 Scented menstrual tampon.**

(a) *Identification.* A scented menstrual tampon is a device that is a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge. It has scent (i.e., fragrance materials) added for aesthetic purposes. This generic type of device does not include menstrual tampons treated with added antimicrobial agents or other drugs.

(b) *Classification.* Class II (performance standards).

**§ 884.5470 Unscented menstrual tampon.**

(a) *Identification.* An unscented menstrual tampon is a device that is a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge. This generic type of device does not include menstrual tampons treated with scent (i.e., fragrance materials) or those with added antimicrobal agents or other drugs.

(b) *Classification.* Class II (performance standards).

**§ 801.430 User labeling for menstrual tampons.**

(a) This section applies to scented or scented deodorized menstrual tampons as identified in § 884.5460 and unscented menstrual tampons as identified in § 884.5470 of this chapter.

(b) Available data show that toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstrual tampons. To protect the public and to minimize the serious adverse effects of TSS, menstrual tampons shall be labeled as set forth in paragraphs (c) and (d) of this section.

(c) If the information specified in paragraph (d) of this section is to be included as a package insert, the following alert statement shall appear prominently and legibly on the package label:

> *Attention: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.*

(d) The consumer information required by this section shall appear prominently and legibly, in a package insert or on the package, in terms understandable by the layperson and shall include statements concerning:

(1)(i) Warning signs of TSS, e.g., sudden fever (usually 102° or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;

(ii) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;

(2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to women under 30 years of age and teenage girls, the estimated

incidence of TSS of 6 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;

(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow;

(4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and possibly reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and

(5) The need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.

(e) Any menstrual tampon dispensed by a vending machine is exempt from the requirements of this section.

(f) Any menstrual tampon that is not labeled as required by this section and that is initially introduced or initially delivered for introduction into commerce after December 20, 1982, is misbranded pursuant to sections 502(a) and 201(n) of the act.

**§ 801.430 User labeling for menstrual tampons.**

(a) This section applies to scented or scented deodorized menstrual tampons as identified in § 884.5460 and unscented menstrual tampons as identified in § 884.5470 of this chapter.

(b) Data show that toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstrual tampons. To protect the public and to minimize the serious adverse effects of TSS, menstrual tampons shall be labeled as set forth in paragraphs (c), (d), and (e) of this section and tested for absorbency as set forth in paragraph (f) of this section.

(c) If the information specified in paragraph (d) of this section is to be included as a package insert, the following alert statement shall appear prominently and legibly on the package label:

> *ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.*

(d) The labeling of menstrual tampons shall contain the following consumer information prominently and legibly, in such terms as to render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use:

(1)(i) Warning signs of TSS, e.g., sudden fever (usually 102° or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;

(ii) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;

(2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to

women under 30 years of age and teenage girls, the estimated incidence of TSS of 1 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;

(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS;

(4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and

(5) The need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.

(e) The statements required by paragraph (e) of this section shall be prominently and legibly placed on the package label of menstrual tampons in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (unless the menstrual tampons are exempt under paragraph (g) of this section).

(1) Menstrual tampon package labels shall bear one of the following absorbency terms representing the absorbency of the production run, lot, or batch as measured by the test described in paragraph (f)(2) of this section;

| Ranges of absorbency in grams[1] | Corresponding term of absorbency |
|---|---|
| 6 and under | Junior absorbency. |
| 6 to 9 | Regular absorbency. |
| 9 to 12 | Super absorbency. |
| 12 to 15 | Super plus absorbency. |
| 15 to 18 | None. |
| above 18 | None. |

[1]These ranges are defined, respectively, as follows: less than or equal to 6 grams; greater than 6 grams up to and including 9 grams; greater than 9 grams up to and including 12 grams; greater than 12 grams up to and including 15 grams; greater than 15 grams up to and including 18 grams; and greater than 18 grams.

(2) The package label shall include an explanation of the ranges of absorbency and a description of how consumers can use a range of absorbency, and its corresponding absorbency term, to make comparisons of absorbency of tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS.

(f) A manufacturer shall measure the absorbency of individual tampons using the test method specified in paragraph (f)(2) of this section and calculate the mean absorbency of a production run, lot, or batch by rounding to the nearest 0.1 gram.

(1) A manufacturer shall design and implement a sampling plan that includes collection of probability samples of adequate size to yield consistent tolerance intervals such that the probability is 90 percent that at least 90 percent of the absorbencies of individual tampons within a brand and type are within the range of absorbency stated on the package label.

(2) In the absorbency test, an unlubricated condom, with tensile strength between 17 Mega Pascals (MPa) and 30 MPa, as measured according to the procedure in the American Society for Testing and Materials (ASTM), D 3492-83, "Standard Specification for Rubber Contraceptives (Condoms)"[1] for determining tensile strength, which is incorporated by reference in accordance with 5 U.S.C. 552(a), is attached to the large end of a glass chamber with a rubber band (see Figure 1) and pushed through the small end of the chamber using a smooth, finished rod. The condom is pulled through until all slack is removed. The tip of the condom is cut off and the remaining end of the condom is stretched over the end of the tube and secured with a rubber band. A preweighed (to the nearest 0.01 gram) tampon is placed within the condom membrane so that the center of gravity of the tampon is at the center of the chamber. An infusion

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1 Copies of the standard are available from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 1100 L St., N.W., Washington, DC.

needle (14 guage) is inserted through the septum created by the condom tip until it contacts the end of the tampon. The outer chamber is filled with water pumped from a temperature-controlled waterbath to maintain the average temperature at 27 ± 1 °C. The water returns to the waterbath as shown in Figure 2. Syngyna fluid (10 grams sodium chloride, 0.5 gram Certified Reagent Acid Fuchsin, 1,000 milliliters distilled water) is then pumped through the infusion needle at a rate of 50 milliliters per hour. The test shall be terminated when the tampon is saturated and the first drop of fluid exits the apparatus. (The test result shall be discarded if fluid is detected in the folds of the condom before the tampon is saturated). The water is then drained and the tampon is removed and immediately weighed to the nearest 0.01 gram. The absorbency of the tampon is determined by subtracting its dry weight from this value. The condom shall be replaced after 10 tests or at the end of the day during which the condom is used in testing, whichever occurs first.

(3) The Food and Drug Administration may permit the use of an absorbency test method different from the test method specified in this section if each of the following conditons is met:

(i) The manufacturer presents evidence, in the form of a citizen petition submitted in accordance with the requirements of § 10.30 of this chapter, demonstrating that the alternative test method will yield results that are equivalent to the results yielded by the test method specified in this section; and

(ii) FDA approves the method and has published notice of its approval of the alternative test method in the FEDERAL REGISTER.

(g) Any menstrual tampon intended to be dispensed by a vending machine is exempt from the requirements of this section.

(h) Any menstrual tampon that is not labeled as required by paragraphs (c), (d), and (e) of this section and that is initially introduced or initially delivered for introduction into

commerce after March 1, 1990, is misbranded under sections 201(n), 502 (a) and (f) of the act.

(Information collection requirements contained in paragraphs (e) and (f) were approved by the Office of Management and Budget under control number 0910-0257)

[47 FR 26989, June 22, 1982, as amended at 54 FR 43771, Oct. 26, 1989)

[GRAPHS OMITTED]

[LETTERHEAD OF
DEPARTMENT OF HEALTH & HUMAN SERVICES]

February 20, 1987

Stephen M. McNamara, Esq.
Hyman, Phelps & McNamara, P.C.
1120 G Street, N.W.
Washington, D.C. 20009

Dear Mr. McNamara:

In a meeting today, you brought to my attention an affidavit from Marlys A. Marshall recounting a communication between her and Ms. Beverly Rothstein of my office. The affidavit has been submitted in connection with a lawsuit entitled *Edmondson* v. *International Playtex, Inc.* You have requested that I comment on the affidavit. After discussing the affidavit with Ms. Rothstein, I have the following comment.

Ms. Rothstein's statements pertained to the general issue of whether common law liability for damages for injury would be considered to be a requirement with respect to a medical device within the meaning of 21 U.S.C. § 360k(a) based on prior rulings of the Food and Drug Administration in related situations and did not state what the Food and Drug Administration would officially conclude were it to consider the question in the context of a petition for an advisory opinion. Ms. Rothstein supplied the March 8, 1984, letter from Mr. Paul Hile of FDA to Mr. Robert E. Manchester of the National Women's Health Network to Ms. Marshall as a statement of the agency's position on the specific issue addressed in that letter and conveyed the view that if asked to respond officially on the same type of issue in the future, the agency's position would be consistent. Obviously, what would be consistent would depend on the specific circumstances described. Moreover, although it is generally the case that the agency's interpretations remain uniform over time, it is obviously not possible for a member of the Office of the Chief Counsel to guarantee a specific outcome in a particular case, and certainly no firm prediction would ever be made by

a member of the Office of the Chief Counsel during a casual telephone conversation. It was specifically for that reason that Ms. Rothstein suggested to Ms. Marshall that Ms. Marshall submit a petition for an advisory opinion on the specific issue Ms. Marshall raised.

I should also note that a sentence that includes a reference to the "Chief Counsel" on page 17 of a memorandum (of which you gave me pages 16-17) is erroneous in two respects. Ms. Rothstein was not providing an "informal opinion" (other than in the sense that any statement that is not about facts is an opinion) but was providing assistance to someone wanting information, and Ms. Rothstein was not speaking as the Chief Counsel, but as an Associate Chief Counsel.

According to Ms. Rothstein, Ms. Marshall did not state that Ms. Rothstein's views would be incorporated in an affidavit and submitted in litigation in substitution for an official FDA opinion: Ms. Marshall stated that she was doing research and needed assistance.

I understand that you may use this letter in connection with the litigation and you have my permission to do so.

Sincerely yours,

/s/ THOMAS SCARLETT

Thomas Scarlett
Chief Counsel
Food and Drug Administration